

## **R E M A R K S**

The Applicants note that all amendments and cancellations of Claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

The Examiner has requested affirmation of the telephone election of Group I (Claims 1-11) for prosecution in the present case (Office Action, pg. 2). The Applicants affirm their election of Claims 1-11 without traverse. Claims 12-15 have been withdrawn by the Examiner.

In the Office Action dated 12/20/05, the Examiner issued two rejections. Each of the rejections is discussed below.

The Examiner has stated that the previously filed Invention Disclosure Statement of 05/10/2004 failed to comply with 37 CFR 1.98(a)(2). Applicants respectfully submit that the initial Invention Disclosure Statement was properly submitted, and attach a photocopy of the return receipt postcard which demonstrates that the USPTO did receive the correctly filed Invention Disclosure Statement. However, a new copy of the Invention Disclosure Statement is included with this Office Action Response for the Examiner's convenience. The Applicants do not believe additional fees are required, however if additional fees are required please utilize the Applicant's established USPTO account for fee dispersal.

### **I. The Claims are Definite**

The Examiner rejects Claims 1 and 3-11 under 35 U.S.C. 112, second paragraph, as allegedly being incomplete for omitting essential steps (Office Action, pg. 3). The allegedly omitted steps are: a correlation step describing how the results of the method relate back to the preamble of the method objectives. The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 1 to include additional language that relates the method back to the method preamble. As such, the Applicants believe that the rejection should be withdrawn.

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept., 8, 2000).

The Examiner rejects Claims 1 and 3-11 under 35 U.S.C. 112, second paragraph, as allegedly being vague and indefinite (Office Action, pg. 3). In particular, the Examiner states "Claims 2-11 are rejected as vague and indefinite for reciting the term HIP1 as the sole means of identifying the claimed molecule." The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 1 to specify Huntington Interacting Protein 1, the full name of HIP1. As such, the Applicants submit that they have specifically identified the HIP1 recited in the claims. Accordingly, the rejection should be withdrawn.

## **II. The Claims are Enabled**

The Examiner rejects Claims 1-11 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement (Office Action, pg. 4). In particular, the Examiner states "The instant specification is not enabling for claims drawn to detecting any and/or all cancers comprising providing a sample from a subject suspected of having cancer; and detecting the presence or absence of antibodies to HIP1 in said sample, wherein the presence of antibodies to HIP1 is indicative of cancer." The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 1 to specify that the presence of HIP1 antibodies is indicative of prostate cancer in the subject. The Applicants point to Figure 28, which clearly indicates that a greater number of the prostate cancer samples were positive for antibodies to HIP1 than the normal prostate controls. In addition, Example 8 states " This gives the screening test a significance of  $P < 0.025$  (chi squared) and a 75% sensitivity and 61% specificity." (pg. 83, lines 5-6). As such, the Applicants submit that they have demonstrated a correlation between serum antibodies to HIP1 and prostate cancer. Accordingly, the Applicants submit that the claims are enabled and respectfully request that the rejection be withdrawn.

**CONCLUSION**

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

Dated: March 20, 2006



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